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MORRISON	MORRISON & FOERSTER LLP		EXAMI	NER
3811 VALLEY CENTRE DRIVE SUITE 500			KERR, KATHLEEN M	
SAN DIEGO,	CA 92130-2332		ART UNIT	PAPER NUMBER
			1652	
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Please find below and/or attached an Office communication concerning this application or proceeding.

•		Application No.	Applicant(s)
Office Action Summary		09/687,855	KHOSLA ET AL.
		Examiner	Art Unit
		Kathleen M Kerr	1652
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the	correspondence address
A SH THE - Externation of the content of the cont	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1: SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period vere to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be to within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from the application to become ABANDON	timely filed ays will be considered timely. m the mailing date of this communication. IED (35 U.S.C. § 133).
1)⊠	Responsive to communication(s) filed on 30 S	September 2002 .	
2a)⊠	<u> </u>	is action is non-final.	
3)	Since this application is in condition for allowardlosed in accordance with the practice under		
· <u> </u>	ion of Claims		
·	Claim(s) <u>1 and 53-77</u> is/are pending in the app		
	4a) Of the above claim(s) <u>75-77</u> is/are withdraw	vn from consideration.	
·	Claim(s) is/are allowed.		
	Claim(s) <u>1 and 53-74</u> is/are rejected.		
	Claim(s) is/are objected to.		
	Claim(s) are subject to restriction and/or ion Papers	r election requirement.	
• •	The specification is objected to by the Examine	r	
	The drawing(s) filed on is/are: a)☐ accept		aminer
.0,	Applicant may not request that any objection to the	•	
11) 🔲 -	The proposed drawing correction filed on		• •
,_	If approved, corrected drawings are required in rep		
12) 🔲 -	The oath or declaration is objected to by the Ex		
Priority u	ınder 35 U.S.C. §§ 119 and 120		
13)	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a)-(d) or (f).
a)[☐ All b)☐ Some * c)☐ None of:		
	1. Certified copies of the priority documents	s have been received.	
	2. Certified copies of the priority documents	s have been received in Applica	tion No
* S	3. Copies of the certified copies of the prior application from the International Bur Gee the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).	•
14)⊠ A	cknowledgment is made of a claim for domestic	c priority under 35 U.S.C. § 119	(e) (to a provisional application).
) The translation of the foreign language pro		
Attachment			
2) 🔲 Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u>	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)
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U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

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DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 9, mailed on April 9, 2002), Applicants filed a response and amendment received on August 14, 2002 (Paper No. 12). Said amendment amended the specification and Claim 1, cancelled Claims 2-9 24-29, and 42-52, and added new Claims 53-77. New Claims 53-74 are drawn to the previously elected group (elected without traverse in Paper No. 7) and will be examined herein.

Election

2. New Claim 75 is drawn to non-elected Group II (see Paper No. 7) and will not be examined. Newly submitted claims 76 and 77 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The elected invention of Claims 1 and 53-74 is related to Claims 76-77 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cells of the elected invention can be used in a materially different process of using that product, such as in production of polyketides. Thus, the elected invention is patentably distinct from Claims 76-77.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits. Accordingly, claims 76-77 are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

This application contains Claims 75-77 drawn to an invention non-elected without traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/159,090 filed on October 13, 1999, 60/206,082 filed on May 18, 2000 and 60/232,379 filed on September 14, 2000.

Information Disclosure Statement

4. The supplemental information disclosure statement filed on September 30, 2002 (Paper No. 13) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. This IDS is in addition to the previously considered IDS, Paper No. 5, noted in the previous Office action.

Withdrawn - Objections to the Specification

- 5. Previous objection to the specification for lacking proper continuity data citation in the first paragraph is withdrawn by virtue of Applicants' amendment to the first paragraph.
- 6. Previous objection to the specification for containing improper references to application numbers is withdrawn by virtue of Applicants' amendment to the specification updating said application numbers to their respective patent numbers.

Maintained - Objections to the Specification

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7. The objection to the title previously noted is maintained herein. The title, as amended by Applicants, does not adequately describe the claimed subject matter. While some of the *E. coli* cells claimed produce methylmalonyl-CoA (Claims 1 and 53-60), the *Streptomyces* cells and *E. coli* cells of Claims 61-74 have no such requirement. A new, more appropriate title is required.

Withdrawn - Claim Objections

- 8. Previous objection to Claim 9 for a typographical error is withdrawn by virtue of Applicants' cancellation of said claim.
- 9. Previous objection to Claims 4-5 and 27 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.
- 10. Previous objection to Claim 8 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.
- 11. Previous objection to Claim 9 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

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Withdrawn - Claim Rejections - 35 U.S.C. § 112

12. Previous rejection of Claims 1-9, 24-29, and 42-43 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms "polyketide" and "complete polyketide" is withdrawn by virtue of Applicants' cancellation of said claims. The term "polyketide", as used in the amended and/or added claims, is clear in light of the specification and the state of the art.

- 13. Previous rejection of Claims 1-9 and 24-29 under 35 U.S.C. § 112, second paragraph, as being indefinite for the terms "starter unit" and "extender unit" is withdrawn by virtue of Applicants' amendment.
- 14. Previous rejection of Claims 1-9, 24-29, and 42-43 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, particularly the inclusion of a phosphopantetheinyl transferase (ppt) in *E. coli* host cells, is withdrawn by virtue of Applicants' cancellation of said claims. Moreover, the new claims drawn to *E. coli* host cells all require a ppt.
- 15. Previous rejection of Claim 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for lacking proper antecedent basis is withdrawn by virtue of Applicants' cancellation of said claim.
- 16. Previous rejection of Claim 9 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "derived from" is withdrawn by virtue of Applicants' cancellation of said claim.

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17. Previous rejection of Claims 1-9, 24-29, and 42-43 under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, particularly for the genus of proteins catalyzing the production of starter/extender units and the genus of endogenous pathways for catabolism of starter/extender units, is withdrawn by virtue of Applicants' amendment and/or cancellation of the instant claims. The rejection is also withdrawn for the genus of modular polyketide synthase gene clusters based on the Examiner's reconsideration in view of the extensive art, wherein the term dictates not only a function, but also a particular structure in the art.

The rejection of Claim 1 with respect to the genus of phosphopantetheinyl transferases is maintained; however, for clarity's sake, this rejection will be restated below along with rejection of newly pending claims using the same reasoning. Applicants present no arguments particular to this holding of a lack of written description.

18. Previous rejection of Claims 1-9, 24-29, and 42-43 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

19. Previous rejection of Claims 1-3 under 35 U.S.C. § 102(a) as being anticipated by An *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.

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- 20. Previous rejection of Claims 1-3 under 35 U.S.C. § 102(a) as being anticipated by Rodriguez *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.
- 21. Previous rejection of Claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Spratt et al. is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.
- 22. Previous rejection of Claims 1-3 and 8 under 35 U.S.C. § 102(b) as being anticipated by Quadri *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.
- 23. Previous rejection of Claims 1-2, 4, 6-7, 9, and 24-26 under 35 U.S.C. § 102(b) as being anticipated by Kao *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.
- 24. Previous rejection of Claims 1, 4, 9, and 24 under 35 U.S.C. § 102(b) as being anticipated by Stassi *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.
- 25. Previous rejection of Claims 1, 2, 4, 9, and 24 under 35 U.S.C. § 102(b) as being anticipated by Tang *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.

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26. Previous rejection of Claims 1-9, 24-29, and 42-43 under 35 U.S.C. § 102(b) as being anticipated by WO98/27203 (Barr *et al.*) is withdrawn by virtue of Applicants' cancellation and/or amendment of the instant claims.

NEW OBJECTIONS/REJECTIONS

Claim Objections

- 27. Claims 58 and 66 are objected to for a typographical error.
 - a) In Claim 58, the term "prpAD" should be --- prpA-D --- to include the intervening genes B and C as described throughout the specification.
 - b) In Claim 66, only a single mat gene is referenced so "mat genes" should be ---mat gene---.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

28. Claim 55 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the expression system for biotin ligase" does not have proper antecedent basis in the parent claim, Claim 1, and is, thus, confusing. Appropriate clarification is required. It seems evident that Claim 55 should more appropriately depend from Claim 54.

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29. Claim 57 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "has no functional endogenous pathway for propionate catabolism" is wholly unclear as to its metes and bounds. Cellular metabolic pathways are very much intertwined; it is unclear which particular enzymes are encompassed in the disabling of such a broad pathway. Appropriate clarification is required.

30. Claims 59, 60, 67, 68, 73, and 74 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The abbreviations "DEBS" and "6-dEB" are used in the claims without proper definition upon their first occurrence. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

31. Claims 61, 64-69, and 72-74 are rejected under 35 U.S.C. § 112, first paragraph, new matter, and under 35 U.S.C. § 132 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment filed on August 14, 2002 adds new matter to the instant claims as follows.

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as originally filed.

The instant claims are drawn to *E. coli* or *Streptomyces* host cells modified to contain at least a *matB* gene. While the instant specification describes a *matABC* operon from *R. trifoli* and from *S. coelicolor* and describes, by way of Examples 1 and 3, recombinant host cells containing exogenous *matABC* genes, no description of host cells modified with only a *matB* gene is found. All descriptions of the use of this operon describe either the entire operon, *matABC*, or just the two genes, *matBC*, alone. Applicants are required to cancel the added subject matter in response to this Office action or to point out particular support (page and line number) in the specification

32. Claims 1 and 53-74 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to *E. coli* and *Streptomyces* host cells modified by expression systems which host cells are claimed *solely* by function and without any structural limitations. The following is a summary of the genera of expression systems that lack written description and their related claims:

propionyl CoA carboxylase phosphopantetheinyl transferase biotin ligase matABC gene

Claims 1 and 54-60 Claims 1, 53-55, 57-60, and 69-74 Claim 54 Claims 61-65, 67-71, 73, and 74

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and

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Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material or host cell containing genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant claims, genera of expression systems are claimed using a name, such as propionyl CoA carboxylase. This name is indicative of a function, but not particularly a structure. A single example of a propionyl CoA carboxylase expression system is described in the instant specification, namely the *pccB* and *accA2* genes from *S. coelicolor*. This single example does not provide adequate description of the claimed genus since common structural components of the genus are described. For phosphopantetheinyl transferase, the specification describes a single species, *sfp* from *B. subtilis*, useful in the priming of modular PKSs in heterologous systems. This single example does not provide adequate description of the claimed genus since common structural components of the genus are described. For biotin ligase, the specification describes a single species, *birA* from *E. coli*, effective in aiding the assembly of propionyl CoA carboxylase. This single example does not provide adequate description of the claimed genus since common structural components of the genus are described. For malonyl CoA enzymes (decarboxylase, synthetase, and transporter) *matABC*, two examples are cited — one from *S. coelicolor* and one from *R. trifoli*. While multiple examples are described, their

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structural relationship to each other is not, thus the genus is still not described. These two examples do not provide adequate description of the claimed genus since common structural components of the genus are described.

33. Claims 1, 53, 56-60 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for host cells expressing functional propionyl CoA carboxylase as a result of co-expressing biotin ligase, does not reasonably provide enablement for host cells expressing propionyl CoA carboxylase in the absence of co-expressing biotin ligase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The instant claims are drawn to host cells modified to contain an expression system for a functional propionyl CoA carboxylase. To produce such cells in the absence of biotin ligase would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

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experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima* facie case is discussed below.

On page 6 on the instant specification it is noted that biotin ligase is necessary for expression of a functional propionyl CoA carboxylase; the ligase aids in the attachment of biotin to the enzyme (see page 22 of the specification). In Examples 2 and 4 of the instant specification, *in vivo* expression of a functional propionyl CoA carboxylase is accompanied by co-expression of biotin ligase. No examples of such expression are described in the absence of the ligase. The prior art and the specification are wholly silent concerning alternate means of producing a functional propionyl CoA carboxylase. It is wholly unpredictable as to whether there is another means for producing a functional propionyl CoA carboxylase. Thus, the instant claims are not enabled to the full extent of their scope.

34. Claim 57 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for host cells whose *prpA-D* operon is disabled to produce a cell lacking functional, endogenous propionate catabolism, does not reasonably provide enablement for host cells whose endogenous propionate catabolism is somehow otherwise disabled. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The instant claims are drawn to host cells modified to disable their

endogenous propionate catabolism. To produce such cells by means other than disabling the *prpA-D* operon would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification describes so as to enable a single example of host cells whose endogenous propionate catabolic pathway is disabled. The specification provides no guidance as to how else this might be accomplished. The art is such that complicated metabolic pathways exist in *E. coli* so that disabling a certain pathway by nondescript means is wholly unpredictability. Thus, the instant claim is not enabled to the full extent of its scope.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 35. Claims 61-65 and 67-68 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kao et al. (IDS Paper No. 5, reference No. 9). The instant claims are drawn to recombinant S. coelicolor host cells that contain an expression system for matABC and DEBS. The Examiner notes that the product of a host cell "modified to contain" and one that naturally contains the matABC operon are indistinguishable since the process of "modifying", as found in the claim limitations, need to have any particular permanent effect on the claimed product.

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Kao et al. teach recombinant S. coelicolor CH999 host cells modified to contain the DEBS PKS gene cluster. CH999 host cells natively contain S. coelicolor matABC genes, thus, are indistinguishable from host cells modified to incorporate such an expression system.

Allowable Subject Matter

36. The Examiner notes that the concept of precursor feeding in heterologous polyketide systems is not a novel one. In particular, Stassi *et al.* teach that the heterologous expression of a recombinant modular PKS requires the addition of butyryl-CoA, in the form of media supplementation or by means of co-expression of recombinant crotonyl-CoA reductase for the production of butyryl-CoA. While the propionyl CoA carboxylase and malonyl biosynthesis expression systems are recognized as producing PKS precursors (see Rodriguez *et al.*, Hyang *et al.* and GenBank Accession Number AL163003), no direct link between expression systems for these particular precursors and expression systems for modular PKSs is established in the art. Moreover, expression of phosphopantetheinyl transferases such as *sfp* are well know to be required for effective heterologous expression of PKS systems in *E. coli* (see Barr *et al.* in WO98/27203). But again, no direct link between *sfp* expression and propionyl CoA carboxylase or malonyl biosynthesis expression systems is taught or indicated in the prior art.

Conclusion

37. Claims 1 and 53-74 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

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Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK November 9, 2002 PONNETWARE A CHUTE MURTHY
SUPERVICENT CONTENT TECHNOLOGY CENTER 1600